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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,554	07/23/2001	Edmund Scholl	24669	6387

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EXAMINER	
HOWARD, SHARON LEE	

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/857,554	Applicant(s) SCHOLL, EDMUND	
	Examin r Sharon L. Howard	Art Unit 1615	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Examiner acknowledges receipt of one month extension of time and Amendment B filed on 2/3/03.

Claim 42 has been amended.

Claims 22-55 are pending.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for on page 4, [022] of the specification, a composition which can also contain several active ingredients, does not reasonably provide enablement for the phrases "substantially free from other constituents" and "substantially free from salts". It is suggested to applicant that said phrases be inserted into the specification to support the independent claim. The instant specification for example permits other constituents (see page 6, lines 1-3). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (*In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):*

1) The nature of invention

2) The state of the prior art

3) The relative skill of those in the art

4) The predictability or unpredictability of the art

5) The breadth of the claims

6) The amount of direction or guidance presented

7) The presence or absence of working examples

8) The quantity of experimentation necessary

1) The nature of the invention:

The invention provides an active ingredient matrix in the form of a biologically resorbable, porous nonwoven of collagen fibrils in lyophilized form with a retarded release of active ingredients, containing at least one homogeneously distributed active ingredient poorly soluble in water and body fluids, which, apart from the collagen fibrils as the carrier structure and the at least one active ingredient, is substantially free from further constituents, which is substantially free from salt and in which the at least one active ingredient in physiological medium has a solubility of < 10 mg/ml.

2) The state of the prior art:

The prior art does not teach collagen sponges which are combined with commercially obtainable fibrin adhesion systems that are used for arresting

diffuse hemorrhages, particularly in parenchymatous organs. For some years products have been commercially available, which comprise aminoglycoside-filled collagen.

3) The relative skill of those in the art:

The relative skill of those in the art is high because collagen sponges have been clinically used in large numbers for many years. There is a need for creating an active ingredient matrix in which the active ingredient action persists over a long period of time. As such the relative skill of those in the art is high.

4) The predictability or unpredictability of the art:

The unpredictability of the art is high because over the past few years the need for resorbable hemostatics has led to the development of collagen-based products.

5) The breadth of the claims:

Claim 1 is broad. The claim recites an active ingredient matrix which is in the form of a biologically resorbable, porous nonwoven of collagen fibrils in lyophilized form with a retarded release of active ingredients, wherein the active ingredient is poorly soluble in water and body fluids.

6) The amount of direction or guidance presented:

The specification is enabling for the active ingredient matrix which is in the form of a biologically resorbable, porous nonwoven of collagen fibrils in lyophilized form with a long lasting release of active ingredients.

7) The presence or absence of working examples:

See the examples on pages 7-14 (Tables 1-5) of the specification where applicant discloses how other constituents are included in the composition.

8) The quantity of experimentation necessary:

The quantity of experimentation is necessary because on page 4, subpara. [022], at lines 3-6 of the specification, applicant discloses that other active ingredients can be included in the matrix, and the ordinary skilled practitioner would be burdened with undue experimentation to practice the invention.

Claim Rejections - 35 USC § 112

Claims 22-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 22-55, the phrases "substantially free from other constituents" and "substantially free from salts" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is suggested that applicant recite the specific amounts of the active ingredients that are present in composition.

Regarding claim 30, the phrase "it contains at least one less poorly soluble or easily soluble active ingredient" contain relative terms which render the claim indefinite. The term "less" and "easily" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is suggested that applicant quantify the particular amounts of the active ingredient. Clarification is requested.

Regarding claim 46, it is unclear as to what applicant intend to convey since applicant is claiming salts of the compounds "clindamicin-palmitate, clindamicin-palmitate hydrochloride and gentamicin-crobefat" in claim 46. Clarification is requested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3121 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Sharon Howard
Sharon Howard
August 1, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600